

# Brazil

**Trade dress issues in relation to pharmaceutical products have become more apparent in Brazil as trade in generic drugs increases. Luckily, local law provides adequate protection against imitation**

In the past few years, the Brazilian courts have handled numerous trade dress cases involving pharmaceuticals. The number of disputes substantially increased after 1999, when Congress passed the law regulating the commercialization of generic drugs.

Since then, some generic manufacturers have been adopting a more aggressive position towards the imitation of reference medications' trade dress. This policy naturally conflicts with the interests of the brand-name drug companies, adding another chapter to the historical clash between both industries.

In this context, the ability of innovative pharmaceutical companies to challenge the use of lookalike trade dress has become vital. The purpose of this article is thus to provide an overview of pharmaceutical trade dress litigation in Brazil, as well as some practical advice as to the most appropriate ways to protect the trade dress of pharmaceuticals in this important jurisdiction.

## Protecting pharmaceutical trade dress

Under Brazilian practice, protection for pharmaceutical packaging and shapes can be sought under:

- unfair competition law;
- trademark law; and
- regulatory law.

## Unfair competition law

As the Brazilian legal system has no provision expressly conferring protection to the overall appearance of a product, trade dress infringement issues are generally included within the scope of unfair competition law. For this purpose, the trade dress owner can rely on Section 195(III) of the Industrial Property Law and must demonstrate that the adoption of the lookalike trade dress is likely to attract consumers fraudulently and/or confuse them. Although the concept of 'fraudulent attraction' is somewhat broad, Brazilian courts have often granted protection to

unregistered pharmaceutical trade dress based on this provision.

## Trademark law

Pharmaceutical trade dress can be registered as either combination (ie, word and device) or three-dimensional marks at the Brazilian Trademark Office (BTO). This includes packaging, pill shapes and any other visually distinctive feature capable of functioning as an indicator of source. Trademark registration confers on the trade dress owner important legal advantages – namely:

- property rights and the resulting ability to license or sell the trade dress;
- nationwide rights;
- a *prima facie* presumption of distinctiveness;
- a stronger position to obtain preliminary injunctions and other interim orders;
- the prerogative to take criminal measures; and
- the possibility to forum shop and to include retailers or distributors as co-defendants in infringement lawsuits.

For these reasons, pharmaceutical companies are strongly encouraged to register their products' trade dress as trademarks at the BTO.

## Regulatory law

ANVISA, the Brazilian regulatory body for pharmaceutical and public health issues, enacted in 2003 a resolution regulating pharmaceutical packaging (RDC 333). This resolution expressly provides in Section 2.1.6 that no pharmaceutical packaging can contain features, signs, designs, symbols or any other indication that is likely to cause confusion as to the product's nature, quality or source. Although the resolution does not have the binding status of a promulgated statute, it can be used as an important subsidiary argument in infringement lawsuits to contest the use of packaging that is likely to cause confusion with the trade dress of third parties.

## Enforcing exclusive rights

To prevail in a trade dress infringement claim in Brazil, the plaintiff must prove that:

- its trade dress is distinctive; and
- there is a likelihood of confusion or deceptive association.

Distinctiveness is a fundamental prerequisite for claiming trade dress protection because it is intrinsically related to the ability of the trade dress to identify and distinguish the product from other equivalent products of different sources. To be protectable, therefore, the trade dress must be sufficiently distinctive to communicate source identification to the public. Otherwise, there is no basis for legal protection.

A pharmaceutical trade dress can either be inherently distinctive or have acquired distinctiveness through use. Although the BTO is officially reluctant to apply the 'secondary meaning' doctrine, some Brazilian courts have already recognized the concept of acquired distinctiveness and allowed the registration of descriptive signs and shapes that became distinctive through use. For instance, no one is likely to challenge the statement that the blue diamond shape of Viagra tablets has acquired distinctiveness and deserves protection under the terms of the law.

As regards confusion, Brazilian law prohibits not only actual confusion, but also the likelihood of confusion between the products. Thus, although evidence of actual confusion might strengthen the plaintiff's position, establishing the likelihood of confusion is sufficient to prevail in a pharmaceutical trade dress dispute.

The most common type of confusion occurs when a later entrant to the market tries to misrepresent its product as being the product of its better-known competitor. This is a sort of passing off and Brazilian courts have already held it illegal in many precedents involving pharmaceutical products (eg, *Sanofi v HB Farma* (2003), *Sanofi v Vitapan* (2006)).

Case law also encompasses situations where the junior product is not passed off as the branded drug, but there is either confusion as to its source or simply an unconscious association between the products. In such cases, the courts have acknowledged that although the generic drug is unlikely to be mistaken for the

reference drug, the unauthorized imitation should be prohibited as it is illegally free riding on the competitor's goodwill and reputation.

In *Bristol-Myers v EMS* (2007), a case involving the overall appearance of Bristol Myers's DERMODEX skin rash ointment, the court held that "the consumer will have no doubt that the medication is generic, but may be unsure whether or not it is a generic drug manufactured by the laboratory he [or she] trusts or perhaps may feel familiarity with the product simply because it looks like the reference product... Generating confusion as to source in practice causes fraudulent attraction of consumers, because the defendant is taking advantage of the marketing investments made by the plaintiffs, thus achieving a favourable perception in... consumers' minds (aspects such as trust, tradition and market leadership)."

In *Wyeth v EMS* (2007), a case concerning the trade dress of painkiller Advil, the Rio de Janeiro Court of Appeals upheld a preliminary injunction against an infringing product noting that "the packaging is a marketing tool and constitutes the group of colours and words selected by professionals to set a specific image in the consumers' minds; it is usually built over years of advertisement, so generic medications may not use a trade dress with the same overall impression with similar colours, fonts and details".

Thus, in Brazil, the likelihood of confusion in pharmaceutical trade dress disputes should be examined not only from the passing off perspective, but also with regard to confusion as to source and other unfair advantages that the unauthorized use of the lookalike trade dress might present.

### Functionality

With regard to pill shapes, functionality is also an important aspect to be considered. Pills of certain shapes are easier to swallow and cheaper to make. This explains the popularity of round, oval and biconvex shapes for medications. Size is also an obvious limitation, because although there may be variations in size, the margins of those differences are often very small. Finally, some colours may also be limited.

If an element of the pill shape is deemed functional, no trade dress protection for that specific element is available. In this case, the party seeking to assert exclusive rights has the burden of proving that the trade dress as a whole is non-functional and protectable.



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### Generics Act v trade dress rights

Generic manufacturers often argue in trade dress disputes that the use of a similar packaging is beneficial to consumers, since it better indicates to the public the link between the generic medication and the corresponding brand-name drug. Generic manufacturers rely on the Generics Act 1999 and claim that the statute authorizes the use of similar characteristics in the packaging of generic drugs, creating a sort of exemption from trade dress rights.

This argument is unsupportable, because the Generics Act merely regulates the coexistence of reference medications and their generic versions, allowing third parties to manufacture drugs whose patents have expired. No section of the statute authorizes generic manufacturers to copy or reproduce the overall appearance of the reference medications.

The court in *Bristol-Myers v EMS* examined this issue and pointed out that "lawmakers sought to establish a peaceful coexistence between the legal systems that regulate IP rights and the commercialization of generic drugs. This measure is in line with the Brazilian

Constitution, which assures citizens the social right of health, but also protects IP rights... The Generics Act expressly provides exceptions for situations where patent rights have expired. Since it did not do so with regard to the other industrial property rights – trademarks, industrial designs and other distinctive signs – we conclude that these rights remain fully in force".

As a result, there is no conflict between the Generics Act and the Industrial Property Law. Further, the Generics Act creates no exemption that could be interpreted as authorization to infringe trade dress or trademark rights.

### Efforts to change the regulatory system

In the past decade, generic drug companies have gained a substantial portion of the Brazilian pharmaceutical market. They have also become aggressive lobbyists and have been trying to change the regulatory framework for pharmaceutical packaging.

As a result, Bill 23/07 was introduced into Congress in early 2007. The bill's purpose was to allow generic drug manufacturers to use trade dress similar to that of the corresponding reference medications. Some members of Congress, however, voted against the bill based on the IP problems that a law of this type could generate and the bill was ultimately rejected.

In spite of this, further moves from the generic industry in this direction are expected, so it is imperative for brand-name drug companies to keep a close eye on this issue and prevent any change to the current regulatory environment.

### Conclusion

Given the vigorous competition between brand-name and generic drug companies, and the increasing aggressiveness of the latter towards trade dress imitation, these disputes will doubtless continue. As has been seen, Brazilian law provides many tools to fight this kind of infringement. Further, the Brazilian courts have been granting an adequate level of protection to pharmaceutical trade dress and, most importantly, relevant precedents recognize that the Generics Act should not be interpreted as a green light to infringe trade dress rights. The expectation is that case law will continue to develop in this direction, thereby confirming the ability of innovative pharmaceutical companies to protect their trade dress and discouraging the misappropriation of the goodwill developed in the relevant products. [WTR](#)